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Via E-Mail

The Honorable Dennis M. Cavanaugh
Special Master
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Re: *United States ex rel. Simpson v. Bayer Pharmaceutical Corp., et al.*
Civil Action No. 2:05-cv-03895 (JMZ) (JAD)

Dear Judge Cavanaugh:

The United States respectfully submits this letter brief in Opposition to Bayer's motion for reconsideration ("Bayer Recons.") asking this Court to reconsider Your Honor's March 26, 2020 order granting the Government's motion to quash the third party subpoena served on the Centers for Medicare and Medicaid Services ("CMS") ("Order"). In addition, pursuant to Fed. R. Civ. P. 45(d)(2)(B)(ii) and 45(d)(1), the United States respectfully requests that the Court shift to Bayer the significant costs and expenses CMS has incurred, and continues to incur, as a result of Bayer's subpoena. In support of this request, the United States respectfully submits the Second Supplemental Declaration of Chris Klots ("Klots Second Suppl. Decl.") (attached as Exhibit 1).

Having failed to demonstrate that any of the 275,000 boxes containing the aged paper records are relevant to its defenses in this matter, Order at 10, Bayer seeks to impose further delay and expense on CMS by asking the Court to reconsider its sound Order and Opinion. But Bayer has altogether failed to meet its "high burden" to prevail on a motion for reconsideration by demonstrating either (1) an intervening change in controlling law; (2) the availability of new evidence not available previously; or (3) the need to correct clear error of law or prevent manifest injustice.

Instead, dissatisfied with the Court's ruling, Bayer seeks to re-litigate old arguments, which the Court did not overlook, and to assert new arguments it could have raised previously, but did

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not. Bayer's so-called proposals to lessen the burden of its subpoena are illusory and come far too late. In the meantime, with each delay, CMS faces substantial disruption and escalating costs as a result of Bayer's vastly overbroad and unduly burdensome subpoena.

In light of the documented burden, disruption, and significant expense to CMS, and Bayer's failure to demonstrate the relevance of the aged paper records or that reconsideration of the Court's relevancy ruling is remotely justified, the United States respectfully requests that the Court deny Bayer's motion for reconsideration and uphold its order "quash[ing] Bayer's subpoena to the extent it applies to the aged Medicare paper records dating from 1996 through 1999." Order at 12. The United States also respectfully requests that the Court rule on Bayer's motion expeditiously and immediately lift the stay of its Order so that CMS may proceed with its planned activities without delay.

Finally, because Bayer's subpoena has imposed significant burden and expense on CMS, including the now-impending loss of appropriated funds and continued, unnecessary storage costs, the United States respectfully requests that the Court shift these costs to Bayer pursuant to Fed. R. Civ. P. 45(d)(2)(B)(ii) and 45(d)(1).

LEGAL STANDARD

"Reconsideration is an extraordinary remedy that is granted very sparingly." *Rich v. State*, 294 F. Supp. 3d 266, 272 (D.N.J. 2018) (quotations omitted). A party seeking reconsideration must demonstrate at least one of the following: "(1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court [initially ruled]; or (3) the need to correct a clear error of law or fact to prevent manifest injustice." *Max's Seafood Café v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999); *ABS Brokerage Servs. v. Penson Fin. Servs., Inc.*, No. 09-4590, 2010 WL 3257992, at *6 (D.N.J. Aug. 16, 2010).

A motion for reconsideration "may not be used to re-litigate old matters, nor to raise arguments or present evidence that could have been raised prior to the entry of judgment." *P. Schoenfeld Asset Mgmt., LLC v. Cendant Corp.*, 161 F. Supp. 2d 349, 352 (D.N.J. 2001). Furthermore, a motion for reconsideration must raise more than a party's mere disagreement with a court's initial decision. *See ABS Brokerage Servs.*, 2010 WL 3257992, at *6; *see also P. Schoenfeld*, 161 F. Supp. 2d at 353. When a party claims that the Court overlooked a particular factual or legal issue, "[o]nly dispositive factual matters and controlling decisions of law which were presented to the court but not considered on the original motion may be the subject of a motion for reconsideration." *See id.*

The movant bears a high burden, which cannot be satisfied through "recapitulation of the cases and arguments considered by the court before rendering its original decision." *United States v. Cephalon, Inc.*, 159 F. Supp. 3d 550, 555 (E.D. Pa. 2016) (citations omitted). "[A] motion for reconsideration addresses only factual and legal matters that the Court may have overlooked," and it is "improper on a motion for reconsideration to ask the Court to rethink what it had already thought through—rightly or wrongly." *Glendon Energy Co. v. Borough of Glendon*, 836 F. Supp. 1109, 1122 (E.D. Pa. 1993) (citations omitted) (quotations omitted).

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ARGUMENT

1. This Court Did Not Overlook Categories of “Potentially Relevant” Aged Paper Documents In Its Order

Contrary to Bayer’s contention, this Court did not “overlook” categories of “potentially relevant” aged paper documents. As an initial matter, the Court correctly ruled, and Bayer does not dispute, that “the burden remains on the party seeking discovery to ‘show that the information sought is relevant to the subject matter of the action and may lead to admissible evidence.’” Order at 8 (citing *Caver v. City of Trenton*, 192 F.R.D. 154, 159 (D.N.J. 2000)). Bayer thus had to show the *relevance* of the aged paper records – a burden it did not meet in its Response in opposition to the Government’s motion to quash. Rather, Bayer simply asserted, without explanation, that the aged paper records are “potentially relevant.” See Bayer’s Response in Opposition to Motion to Quash dated February 26, 2020 (“Bayer Opp’n Quash”) at 7. The Court thus correctly held that “Bayer has not met its burden to demonstrate that the boxes containing the aged paper records are relevant.” Order at 10. The Court also correctly ruled that “an assertion [that documents are potentially relevant] is not sufficient to establish Bayer’s burden of proving relevancy.” *Id.* at 11.

In its motion for reconsideration, Bayer has not even attempted to argue that that the Court’s relevancy ruling was legally incorrect, much less that it constituted a “clear error of law or fact” such that reconsideration is necessary to “prevent manifest injustice.”

In its Order, the Court found, and Bayer does not dispute, that the boxes containing aged paper records from 1996, 1997, and 1998 fall outside “the discovery period germane to this case” because the relator’s Tenth Amended Complaint only alleges “fraudulent claims for Trasylol on or after August 5, 1999 and fraudulent claims for Avelox on or after July 24, 2000.” Order at 10–11. Thus, the Court concluded that these boxes “are outside the discovery period and not relevant to Bayer’s claims.” *Id.* at 11. This ruling covers all boxes that pre-date August 5, 1999, regardless of category. Bayer has offered no explanation or basis for reconsideration of the Court’s correct decision in this regard.

As for boxes within the short time period from August 5, 1999 through December 1999, the Court concluded that Bayer had “failed to demonstrate that these boxes contain relevant information that cannot be obtained from other sources.” *Id.* As the Court noted, “Bayer has failed to explain why the information in the National Claims History database is inadequate and why paper records themselves must be provided.” *Id.* The Court observed that “any relevancy arguments are further suspect in light of the fact that the aged paper records do not include information related to payment decisions on the claims.” *Id.* The Court found it “difficult to ascertain how Bayer could ‘learn whether the Government consistently refuses to pay claims in the mine run of cases based upon noncompliance with the two legal requirements at issue’ when payment decisions are not included with the aged paper records.” *Id.* Bayer again offers no explanation or basis for reconsideration of the Court’s correct findings.

Having failed to meet its burden of demonstrating *actual* relevance, Bayer asserted in its opposition to the Government’s motion to quash that the aged paper records may contain “potentially relevant” information to Bayer’s defense. See Bayer Opp’n Quash at 4–7. But

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the Court rejected this argument, explaining that “[s]uch an assertion is not sufficient to establish Bayer’s burden of proving relevancy.” Order at 11. The Court further ruled that it “will not subject the Government to a fishing expedition whereby it is required to conduct a page-by-page review of the contents of 275,000 boxes containing aged paper records in the chance that there are ‘potentially relevant’ documents contained therein.” *Id.* Bayer has offered no explanation or basis for reconsideration of the Court’s correct ruling.

Even though the Court’s Order clearly addresses all the aged paper records from 1996 through 1999, Bayer now asserts that the Order does not address the relevance of the full contents of the boxes. *See* Bayer Recons. at 3–4. Bayer’s arguments are meritless and fall far short of justifying reconsideration.

As an initial matter, Bayer raises a new argument in its motion for reconsideration—that “[p]otentially relevant” material is what the parties are obligated to preserve under the Federal Rules.” Bayer Recons. at 3–4. The Court should reject this argument because a motion for reconsideration is not the appropriate time to raise a new argument and because it improperly conflates the obligation of a party to preserve documents under the Federal Rules with the burden of a party seeking discovery to demonstrate relevance. Even under the very cases it cites, Bayer, as the party seeking discovery, had the burden of establishing the relevance of the requested information. *See Rosa-Diaz v. Harry*, 2019 WL 4464094, *3 (M.D. Pa. Sept. 18, 2019) (“[a] party moving to compel discovery bears the initial burden of proving the relevance of the requested information”); *Nat’l Retail Sys., Inc. v. Markel Ins. Co.*, 2019 WL 1960868, *2 (E.D. Pa Apr. 25, 2018) (“[a] party moving to compel discovery bears the initial burden of establishing the relevance of the requested information”). These cases do not suggest that this burden can be met simply by asserting that the requested documents are “potentially relevant.” Nor do these cases suggest that, once the Court concludes the documents are not relevant, as this Court did, a non-party has an obligation to maintain irrelevant documents.

Bayer also points to a certain number of boxes where the specific contents are not known. *See* Bayer Recons. at 3. But this is a red herring and a rehash of its prior arguments. As the Court has already explained, the paper records do not reflect payment decisions by CMS and therefore are not relevant to the materiality inquiry. To the extent the date range of the box contents is not known, they will be retained until the date range of the box can be ascertained.

Bayer points to other boxes aside from submitted paper claims, arguing that “the Government’s knowledge of the use of Trasyolol in a particular procedure could be established through submitted medical records, correspondence with providers, or appeal files – all of which Mr. Klots says are in the boxes.” *See id.* at 4. This argument is spurious. It is not the Government’s knowledge of the use of Trasyolol that is relevant to the materiality inquiry, but “actual knowledge that certain requirements were violated” that is arguably relevant under *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003–05 (2016) (*Escobar*) and this Court’s April 23, 2019 decision. *United States ex rel. Simpson v. Bayer*, 376 F. Supp. 3d, 392, 415 (D.N.J. 2019).

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Bayer also argues that the “boxes contain other categories of potentially relevant documents aside from paper claims” and speculates that “*Government knowledge about the allegations in this case* could be discerned by internal CMS reports, investigation files, cancelled checks, and remittance advices – all of which Mr. Klots says are in the boxes.” Bayer Recons. at 4 (emphasis added). But this argument is equally meritless.

First, any “internal CMS reports, investigation files, cancelled checks, and remittance advices” from 1996 to 1999 predate the relator’s *qui tam* complaint filed in August 2005 by several years. For this reason alone, such paper records cannot possibly contain evidence of the “Government’s knowledge about the allegations in this case,” as Bayer argues. *Id.* Second, under *Escobar* and this Court’s April 23, 2019 ruling, Bayer must offer “proof that ‘the Government pays a particular claim in full despite its *actual knowledge* that certain requirements were violated’ or ‘regularly pays a particular type of claim in full despite its *actual knowledge* that certain requirements were violated, and has signaled no change in position.’” *Bayer*, 376 F. Supp. 3d at 415 (emphasis added) (quoting *Escobar*, 136 S. Ct. at 2003–05).

Bayer’s argument for discovery focuses not on “actual knowledge that certain requirements were violated,” as set forth in *Escobar*, but on the Government’s knowledge of the “*allegations in this case*.” It is well settled, however, that “actual knowledge that certain requirements were violated” is not the same as awareness of *allegations* of violations. *See United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) (“mere awareness of allegations concerning non-compliance is different from knowledge of actual non-compliance”); *United States ex rel. Rahimi v. Rite Aid Corp.*, 2019 WL 1426333, *8 (E.D. Mich. Mar. 30, 2019) (“Rite Aid’s argument conflates ‘actual knowledge that certain requirements were violated’ with actual knowledge of allegations that certain requirements were violated”); *United States ex rel. Brown v. Pfizer, Inc.*, 2017 WL 1344365, *11 (E.D. Pa April 17, 2017) (“mere knowledge of allegations regarding noncompliance is insufficient to prove actual knowledge of noncompliance”).

Bayer also fails to address how documents that likely do not concern Trasyolol or Avelox, and which do not contain payment decisions, can have any bearing on the materiality inquiry which focuses on the impact of non-compliance on the Government’s payment decisions with respect to those particular drugs. *See* ECF No. 363-1, Klots’ Decl. ¶ 17 (an electronic search of the manifests across 523,000 boxes identified no matches for the words “Trasyolol” or “Avelox”).

If Bayer were genuinely interested in the Government’s payment decisions, it would opt for information in the National Claims History electronic database. *See* Order at 11. As noted by the Court, Bayer has not explained why the information in this database is inadequate. *Id.* As this Court also noted, Bayer’s relevancy arguments are “further suspect” as “[i]t is difficult to ascertain how Bayer could ‘learn whether the Government consistently refuses to pay claims in the mine of run cases based on noncompliance with the two legal requirements at issue’ when payment decisions are not included with the aged paper records.” *Id.*¹ The Court’s observation highlights

¹ Bayer subpoenaed the Government *before* this Court issued its summary judgment decision outlining the materiality standard requirements in this case under *Escobar*, not in response to that ruling as it now claims. *See* Bayer Recons. at 1–2 (“Armed with this statement of the law (referring to this Court’s **April 23, 2019** decision), on **March 13, 2019**,

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what the Government has long suspected—Bayer’s vastly overbroad subpoena was not intended to elicit information relevant to its defense; rather, it was a vehicle to burden and pressure the Government into seeking a dismissal of relator’s complaint under 31 U.S.C. § 3730(c)(2)(A).

2. Bayer’s “Proposals” are Untimely, Self-Serving and Do Not Relieve the Government of Any Burden

Bayer once again raises the issue of sampling, a point the Court expressly noted in its Order granting the Government’s motion to quash. Bayer repeats its belated willingness to review a sample of the aged paper records, but never explains why it refused the opportunity to inspect a sampling of the aged paper boxes during the meet and confer process in July and August 2019.

As described in the Government’s Letter Brief in support of its motion to quash, in a letter dated July 26, 2019, CMS offered to make a “significant sampling of these boxes of aged documents available to [Bayer].” *See* ECF No. 363-5. CMS repeated its offer in a subsequent conference call with Bayer on August 8, 2019, and again in a letter dated August 16, 2019. But Bayer rejected that opportunity, complaining of the expense, casting doubt on its genuine interest in the aged paper records in the first place. Bayer’s refusal to inspect a sample and its refusal to narrow the subpoena left the Government with no choice but to seek relief from this Court through its motion to quash, which was filed on October 3, 2019.

It was not until October 21, 2019, almost three weeks *after* the Government filed its motion to quash, that Bayer expressed for the very first time a willingness to “*discuss* [CMS’s] proposal and *potentially* to proceed in that manner.” *See* Bayer Opp’n Quash, Exhibit C at 3 (emphasis added). To be clear, even then, Bayer did not actually agree to inspect a sample. Rather, it imposed additional conditions and qualifications on its willingness to consider CMS’s proposal. *See id.* Given Bayer’s prior intransigence and unwillingness to narrow the scope of its subpoena, necessitating relief from the Court, CMS believed that further discussions about a sample would only “invite further delay and will likely result in disputes that will inevitably have to be addressed by the Court.” CMS, instead, offered its own counter-proposal, which Bayer did not accept. *See* Bayer Opp’n Quash, Exhibit D at 2.

At this late date, given the current travel restrictions and the agency’s priorities related to the ongoing national emergency over COVID-19, it is not feasible for CMS to arrange for an inspection of a sample in the near future. Furthermore, Bayer’s belated request to inspect a sample, after it refused to do so during the meet and confer process, and after the Court has now found the documents to be irrelevant, comes far too late and does nothing to lessen the Government’s urgent and ongoing need for relief. Moreover, granting Bayer’s request at this late date would enable Bayer to benefit from its prior intransigence, provide Bayer with yet another avenue to create further delays, and entangle CMS in disputes with Bayer on a host of issues such as sample size, representativeness, location – all over documents the Court has already found to be irrelevant.

Bayer served a subpoena on CMS in order to gather the information necessary to understand the Government’s ‘actual or likely conduct,’ the Government’s actual knowledge, and other pertinent issues.”).

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As one court observed when confronted with similar conduct, “to allow [Bayer] now to seek shelter from a fallback position that [the Government] previously tendered in good faith would make a mockery of both parties’ obligation to meet and confer in good faith from the start.” *Bos. Sci. Corp. v. Lee*, No. 1:13-CV-13156-DJC, 2014 WL 3851157, at *7 (N.D. Cal. Aug. 4, 2014). “The time to tap flexibility and creativity is during meet and confer, not after.” *Id.*

Bayer also repeats its argument that “CMS could stipulate to basic facts confirmed by CMS’s productions and its position during meet-and-confer calls.” Bayer Recons. at 5. In its Order, the Court acknowledged that Bayer had suggested such a stipulation. *See* Order at 6. But the Court correctly did not view such a suggestion to relieve Bayer of its burden to establish the relevance of the aged paper records, which Bayer failed to do. Moreover, as CMS previously explained, it could not enter into Bayer’s suggested stipulation because the stipulation was inaccurate and irrelevant. *See* ECF No. 368, Government’s Reply Letter Brief at 4–5.²

Furthermore, the Government categorically disputes Bayer’s unsupported statement that “CMS’s attorneys and productions have confirmed that such a stipulation would be true[.]” Bayer Recons. at 5. Counsel for CMS repeatedly advised Bayer that any such representation that “CMS has never denied payment” was not possible. Indeed, counsel for CMS do not possess the personal knowledge to make such a broad, binding, and unequivocal representation about every claim ever processed by Medicare. Counsel for CMS also has advised Bayer that they lack the legal authority under HHS *Touhy* regulations to make a binding factual representation regarding every claim processed by Medicare on behalf of CMS. *See* 45 C.F.R. §§ 2.3, 2.4. In a declined *qui tam* action, these regulations require (i) a formal request in writing for specific testimony; (ii) authorization of such testimony by the Agency Head or a specified designee of the Agency Head for purposes of 45 C.F.R. Part 2. Bayer’s attempt to resuscitate its stipulation proposal is not a “dispositive factual matter” that would result in “manifest injustice” warranting reconsideration.

Bayer’s request to stay its Order on the motion for reconsideration to take the deposition of Mr. Klots is yet another effort at delay and should similarly be denied. Bayer makes this request for the very first time in its motion for reconsideration nearly nine months after CMS provided Bayer with Mr. Klots’ July 16, 2019 memorandum documenting the contents of the aged paper boxes and the burden of retaining them, and more than six months after the Government filed its motion to quash. Bayer has provided no reason for its untimely request, and the Government respectfully requests that the Court reject it.

² CMS processes hundreds of millions of Medicare Part A and Part B claims each year through automated processing systems. CMS denies claims routinely and for a variety of reasons, including, for example, because an item or service is not “reasonable and necessary.” Furthermore, the Government also takes action to recover overpayments whether through error or fraud. In addition, the Government pursues False Claims Act cases arising from violations of the AKS and the “reasonable and necessary” requirements as applied to off-label uses, the violations at issue in this case.

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3. Under Rule 45, Bayer Must Bear CMS's Significant Expense Resulting From Compliance With Its Subpoena

The United States respectfully requests that the significant costs and expenses that CMS, a non-party,³ has incurred, and is continuing to incur, as a result of Bayer's subpoena be shifted to Bayer pursuant to Fed. R. Civ. P. 45(d)(1) and 45(d)(2)(B)(ii). The United States does not take this step lightly, but having incurred significant storage expense as a result of this subpoena, CMS is now also faced with the imminent loss of millions of dollars in appropriated funds obligated for the purpose of disposing of the aged paper records. Taking into account Bayer's vastly overbroad subpoena, the significant costs and burdens it has imposed on CMS, and Bayer's refusal to adopt reasonable measures to reduce those costs and burdens, cost shifting under Rule 45 is warranted.

Rule 45(d)(1) provides that "[a] party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to a subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction. . . on a party or attorney who fails to comply." (emphasis added).

Bayer has taken no steps to lessen the burden and expense of its overbroad subpoena, which covers 25 years and over 687 million pages of irrelevant aged paper records. First, after CMS brought the aged paper records issue to Bayer's attention in June 2019, it provided Bayer with as much information as possible in the hope that Bayer would agree to narrow the scope of the subpoena to the time period of the complaint. Bayer refused to do so, dismissing the government's burden concerns because "[t]he United States remains a real party in interest and could have dismissed [the relator's case] at any time." *See* ECF No. 363-7, Exhibit 6 at 3, Letter from James Perez to Eden Heard dated Aug. 23, 2019.

Second, during the meet and confer process, CMS repeatedly offered Bayer the opportunity to inspect a sampling of the aged paper records on July 26, August 8, and again on August 16, 2019. During the meet and confer process, CMS also offered Bayer electronic claims data pursuant to the agency's customary practice. In fact, Relator's counsel submitted such a request, and CMS invited Bayer to collaborate with Relator on a joint request and to share the costs. Bayer's refusal to pursue either option calls into question its genuine interest in obtaining the information.

Finally, this Court has correctly recognized that sifting through 275,000 boxes "in the chance that there are 'potentially relevant' documents contained therein" is nothing short of a "fishing expedition." Order at 11. Bayer's "fishing expedition" has severely burdened CMS, disrupted its operations at a critical time, and imposed significant and unnecessary expense in the loss of appropriated funds and needless and unnecessary storage expense. *See* ECF No. 363-1, Klots Decl. ¶¶ 31–38. From the outset, Bayer has known that its subpoena has been disruptive and caused significant expense to CMS. Yet it did nothing to alleviate that burden or expense. Because Bayer has not taken any "reasonable steps to avoid imposing undue burden or expense" to CMS

³ As this Court correctly held, under *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 931 (2009), the United States is not a party to this action. *See* Order at 10.

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from its vastly overbroad and unduly burdensome subpoena for irrelevant documents, it would be appropriate for the Court to shift the costs incurred by CMS onto Bayer under Rule 45(d)(1).

In addition, a court order of compliance with a subpoena “must protect a person who is neither a party nor a party’s officer from significant expense resulting from compliance.” Fed. R. Civ. P. 45(d)(2)(B)(ii). Bayer contends that its subpoena is “an order from the court[.]” *See* Bayer Motion to Compel Production of Documents From the United States Government (March 25, 2020) at 4. CMS submitted timely objections to Bayer’s subpoena and filed its motion to quash. But, pending relief from the Court, CMS complied with Bayer’s subpoena by suspending its disposal of the aged paper records and issuing a subpoena hold. *See* ECF No. 363-1, Klots Decl. ¶ 32. As a direct consequence of complying with Bayer’s subpoena, CMS stands to suffer the loss of appropriated funds and will continue to incur significant storage costs.

Under Rule 45(d)(2)(B)(ii), fee shifting to protect a non-party from significant expense imposed by a subpoena is “mandatory.” *R.J. Reynolds Tobacco v. Philip Morris, Inc.*, 29 F. App’x 880, 882 (3d Cir. 2002); *Linder v. Calero–Portocarrero*, 251 F.3d 178, 182 (D.C. Cir. 2001) (“Rule 45 requires [mandatory fee shifting] – the district court ‘shall protect’ a non-party from ‘significant expense.’”); *Legal Voice v. Stormans Inc.*, 738 F.3d 1178, 1184 (9th Cir. 2013) (“hold[ing] that Rule 45(d)(2)(B)(ii) requires the district court to shift a non-party’s costs of compliance with a subpoena, if those costs are significant”). As succinctly declared by the Ninth Circuit, “the only question before the court in considering whether to shift costs is whether the subpoena imposes significant expense on the non-party. If so, the district court must order the party seeking discovery to bear at least enough of the cost of compliance to render the remainder ‘non-significant.’” *Legal Voice*, 738 F.3d at 1184; *see also R.J. Reynolds*, 29 F. App’x at 883 (“district courts must determine whether the subpoena imposes expenses on a non-party and whether those expenses are significant”). “The rule is susceptible of no other interpretation.” *Linder*, 251 F.3d at 182.

The Government has quantified the timing and loss of appropriated funds and the storage expense CMS has incurred due to Bayer’s subpoena. *See* Klots Second Suppl. Decl. ¶ 8. Even with its efforts to mitigate, CMS will likely and irrevocably lose \$1.4 million in appropriated funds if the Bayer subpoena hold remains in place until May 1, 2020. *See id.* ¶ 9. By June 1, this loss of appropriated funds will rise to \$2.3 million; by July 1, the loss of appropriated funds will rise to \$2.6 million; and by September 1, the loss of appropriated funds will rise to almost \$3 million. *See id.*

In addition, from October 2019, when the United States filed its Motion to Quash, through May 1, 2020, CMS will have incurred at least \$222,000 in storage costs to maintain the aged paper boxes, solely as result of Bayer’s subpoena. *See id.* ¶ 11. This expense will rise to \$282,000 by June 1, 2020, and to \$347,000 by July 1, 2020, with additional storage costs at \$70,000 per month thereafter.⁴ *See id.* ¶¶ 12, 13.

⁴ These costs do not include the costs of conducting a page-by-page review of the contents of 275,000 paper boxes, which could easily exceed 1.3 million labor hours and cost \$70 million. *See* ECF No. 366-1, Suppl, Klots Decl. ¶ 5.

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The combined costs (loss of appropriated funds and storage expense) plainly qualify as significant and cost shifting is warranted. *See Legal Voice*, 738 F.3d at 1185 (having “no trouble concluding that \$20,000 is ‘significant’”); *see also Linder*, 251 F.3d at 182 (concluding that approximately \$200,000 in expenses was “significant” and noting that \$9,000 may be sufficiently significant to justify cost-shifting) (citations omitted).

CONCLUSION

For the foregoing reasons, the United States respectfully requests that this Court deny Bayer’s motion for reconsideration and uphold its March 26, 2020 Order and Opinion “quash[ing] Bayer’s subpoena to the extent it applies to the aged Medicare paper records dating from 1996 through 1999.” The United States also respectfully requests that the Court rule on Bayer’s motion expeditiously and immediately lift the stay of its Order. In addition, the United States respectfully submits that the significant costs and expenses that CMS has incurred, and is continuing to incur, as a result of Bayer’s subpoena warrant shifting those costs to Bayer.

Respectfully submitted,

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